K083470

JAN 23 2009

Edwards

510(k) Summary

Submitter	Edwards Lifesciences LLC
Contact Person	Erica A Walters Regulatory Affairs Associate erica_walters@edwards com (ph) 949-250-2438 (fax) 949-250-3630
Date Prepared	November 20, 2008
Trade Name	Carpentier-Edwards Physio II™ Annuloplasty Ring, Model 5200
Classification Name	Class II, CFR 870 3800 Annuloplasty Ring, KRH
Predicate Device(s)	Carpentier-Edwards Physio™ Annuloplasty Ring (K926138)
Device Description	The Carpentier-Edwards Physio II annuloplasty ring, model 5200, is constructed of cobalt-chromium alloy/polyester film bands with a silicone sewing ring margin covered with a polyester cloth
Indications for Use	The Carpentier-Edwards Physio II annuloplasty ring, model 5200, is intended for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement
Comparative Analysis	It has been demonstrated that the Carpentier-Edwards Physio II annuloplasty ring, model 5200, is comparable to its predicate device in design, intended use, materials, and principal of operation
Functional/Safety Testing	The Carpentier-Edwards Physio II annuloplasty ring, model 5200, has successfully completed design verification testing
Conclusion.	The Carpentier-Edwards Physio II annuloplasty ring, model 5200, is substantially equivalent to its predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Edwards Lifesciences, LLC
Erica A Walters
Regulatory Affairs Associate
One Edwards Way
Irvine CA 92614

JAN 23 2009

Re K083470
Trade/Device Name Carpentier-Edwards Physio II annuloplasty ring, model 5200
Regulation Number 21 CFR 870 3800
Regulation Name Annuloplasty ring
Regulatory Class Class II
Product Code KRH
Dated November 20, 2008
Received November 24, 2008

Dear Ms Walters

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must

comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050 This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083470

Device Name Carpentier-Edwards Physio II Annuloplasty Ring, Model 5200

Indications For Use

The Carpentier-Edwards Physio II Annuloplasty Ring is intended for the correction of mitral valve insufficiency, or mixed mitral insufficiency and stenosis, where treatment does not necessitate a replacement of the natural mitral valve

The Carpentier-Edwards Physio II Annuloplasty Ring is intended to meet the challenges of modern valvuloplasty by maintaining the physiologic annular shape and motion The annuloplasty ring is designed to follow the functional changes which occur during the cardiac cycle, thereby maintaining coaptation and valve integrity in systole while permitting good hemodynamics in diastole

The decision to undertake annuloplasty can be made only after visual analysis of the lesion present The most favorable conditions for annuloplasty using a prosthetic ring are a combination of the distended natural valve ring associated with supple valve cusps and normal chordae tendineae

The remodeling annuloplasty technique with a Carpentier-Edwards Physio II Annuloplasty Ring, Model 5200, may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus, with the exception of severe congenital malformations (e g , AV canal or hypoplastic commissures) or severe degenerative valvular diseases where there is considerable excess tissue

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient However, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae or papillary muscle and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae, or chordal hypertrophy

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochnes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083470